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Sulfur Pesticide Registration Standard

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SULFUR

PESTICIDE REGISTRATION STANDARD

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This document contains information regarding reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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CHAPTER I: HOW TO REGISTER UNDER A REGISTRATION STANDARD

A. Organization of the Standard

This first chapter explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or reregistering under a Standard. The second chapter involves the regulatory position and the rationale supporting this position. The third chapter sets forth the data requirements that must be met to obtain or retain registration for products covered by this particular Registration Standard.

B. Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (and having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

"(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this Act;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks and benefits associated with the use of the proposed pesticide. However, the established approach to making these findings has been found to be defective on two counts.

First, EPA and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a "product by product" basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the "product by product" approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

Second, over the years, as a result of inevitable and continuing advances in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the data files. When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 43 FR 37336, August 22, 1978 and Proposed Data Requirements for Registration Part 158 Subpart B, July 30, 1982), many products that had already

been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency. Congress directed EPA to reregister all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements [See FIFRA Section 3(g)].

Facing the enormous job of re-reviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the "product by product" approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have, compliance with standards of toxicity, composition, labeling, and packaging, and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly-designed label precautions are strictly followed. Thus the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use the pesticide safely, responsibly, and in accordance with label directions. A restricted-use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use," or not classified at all, is available for use by any individual who is in compliance with State or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination is stated in the second chapter.

The Standard will directly register or reregister only manufacturing use products and their intermediaries. End-use products will be registered or reregistered under a separate Label Improvement Program. The only exception to this general rule will arise when there is no manufacturing use product registered for a particular end-use product. In this case, the end-use product will be treated as if it were a manufacturing use product.

The Agency has separated the reregistration of end-use products from that of manufacturing use products in order to increase the rapidity with which products may be reregistered and to place emphasis on the concern for chronic health effects data which prompted the legislative requirement for reregistration. The utility of this approach is the product of two factors. First, end-use product specific data requirements are minimal and can be more effectively handled through a separate process. Second, a separate process obviates many of the difficulties inherent in reregistration of products which are mixtures of more than one active ingredient and will ultimately be affected by several Standards. Under the Label Improvement Program, end-use products will be reregistered on a separate schedule from the reregistration of manufacturing use products.

The Standard will consider all uses of the active ingredient which are registered for end-use products at the time the Standard is developed, including use patterns which pertain only to mixtures. The Standard will also establish labeling requirements for manufacturing use products which formulators of end-use products will have to follow. However, the imposition of these labeling requirements directly on formulators will fall under the Label Improvement Program.

C. Requirement to Reregister under the Standard.

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Congress also agreed that reregistration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for reregistration. His application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies if the registrant fails to comply with the procedures for reregistration set forth in the Guidance Package which accompanies this Standard.

D. "Product Specific" Data and "Generic" Data

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, and Ecological Effects. These determinations are based primarily on the data Guidelines proposed in 43 FR 29696, July 10, 1978; 43 FR 37336, August 22, 1978; and 45 FR 72948, November 3, 1980 and proposed data requirements for registration part 158 subpart 3, July 10, 1982), as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement was actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes,

relatively familiar to registrants. Data which we have found are needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The Standard states which data requirements apply to which product categories. (See the third chapter.) The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

1. Data that are product specific, i.e. data that relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and

2. Generic data that pertains to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks and benefits of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition.

The Agency requires certain "product specific" data for each product to characterize the product's particular composition, physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or reregistration of any manufacturing use product, without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product specific" data on any product other than the applicant's are irrelevant, unless the other product is closely similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluating, with a single set of tests, all products in the group, the Standard so indicates.)

All other data needed to evaluate pesticide products concern the properties or effects of a particular ingredient of products (normally a pesticidally active ingredient, but in some cases a pesticidally inactive, or "inert", ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient [e.g., the acute LD-50 of the active ingredient in its technical or purer grade; see proposed guidelines, 43 FR 37355].

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see, e.g., proposed 40 CFR 163.82-1, 43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use-pattern dependent, it will apply to each manufacturing use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing use product that legally could be used to make an end-use, food-crop pesticide.

If a registrant of a currently registered manufacturing use product wishes to avoid the costs of data compensation [under FIFRA Section 3(c)(1)(D)] or data generation [under Section 3(c)(2)(B)] for "generic" data that are required only with respect to some use patterns, he may elect to delete those

use patterns from his labeling at the time he reregisters his product. An applicant for registration of a new product under this Standard may similarly request approval for only certain use patterns.

E. Data Compensation Requirements under FIFRA 3(c)(1)(D)

Under FIFRA Section 3(c)(1)(D), an applicant for registration, reregistration, or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. The data for which compensation must be offered are all data which are described by all of the following criteria:

1. The data were first submitted to EPA (or to its predecessor agencies, USDA or FDA), on or after January 1, 1970;

2. The data were submitted to EPA (or USDA or FDA) by some other applicant or registrant in support of an application for an experimental use permit, an amendment adding a new use to a registration, or for registration, or to support or maintain an existing registration;

3. They are the kind of data which are relevant to the Agency's decision to register or reregister the applicant's product under the Registration Standard, taking into account the applicant's product's composition and intended use pattern(s);

4. The Agency has found the data to be valid and usable in reaching regulatory conclusions.

An applicant for reregistration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D).

An applicant would never be required to offer to pay for "product specific" data submitted by another firm. In many, if not in most cases, data which are specific to another firm's product will not suffice to allow EPA to evaluate the applicant's product, that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(c)(1)(D) for those data.

Each applicant for registration or reregistration of a manufacturing use product must comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for reregistration (or new registration) under this Standard is found in the Guidance Package for this Standard.

F. Obtaining Data to Fill "Data Gaps"; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have never been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registrability decisions) and have not been located in the published literature search that EPA conducted as part of preparing this Standard. Such instances of missing but required data are referred to in the Standard as "data gaps".

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a section 3(c)(2)(B) order, his product's registration may be suspended until the data are submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in the third chapter, the "generic" data gaps and notes the classes of products to which these data gaps pertain. The Standard also points out that to be registrable under the Standard, a product must be supported by certain required "product specific" data.

As part of the process of reregistering currently registered products, EPA will issue Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps — whether the data in question are "product specific" or "generic" — in accordance with a schedule. Registrants are reminded that Section 6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

G. Amendments to the Standard

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, product chemistry data, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the second chapter. Any

subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies of which may be requested from the Agency.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities. Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identified inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be pointed out in the Guidance Package.

Chapter II

Agency Position on Sulfur

Introduction

This chapter describes in detail the Agency's regulatory position on products which contain sulfur as the sole active ingredient. The regulatory position adopted by the Agency incorporates a number of considerations. Among these considerations are risk criteria found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations and the need for additional data and/or label restrictions. The Agency's determination is presented below, and the rationale for this basic decision follows the position.

In addition to a decision on the registration of the active ingredient and rationale for this decision, this chapter includes the following: criteria for the registration of sulfur products under the Standard; acceptable ranges and limits for product composition, acute toxicity, and use pattern/application method; required labeling; tolerance reassessment.

The data requirements and data gaps are presented in Chapter III, Tables A-C.

Description of Chemical

Sulfur is federally registered as both a fungicide and an insecticide. Between 135-190 million pounds of sulfur is used annually as a pesticide. As a fungicide, sulfur is registered for use on a broad range of agricultural crops and ornamentals to control powdery mildew as well as numerous other foliar diseases and fruit rots.

As an insecticide/miticide, sulfur is used on a variety of field crops, fruits, vegetables and ornamental plants. The major high usage sites include: grapes, peaches, sugarbeets, and citrus. An estimated 60 million pounds of elemental sulfur is used annually as a fertilizer or as a soil amendment for reclaiming alkaline soils.

Sulfur, a non-metallic element that has been known from very early times, is the official common name for this compound. The chemical formula is S and the atomic weight is 32.06. Technical sulfur is a yellow, odorless solid that exists in two allotropic forms - monoclinic (melting point of 119°C) and rhombic crystals (melting point of 112.8°C). Sulfur is practically insoluble in water and slightly soluble in ethanol and ether; the crystalline forms are soluble in CS_2. At room temperature, sulfur is not chemically active. However, when heated, sulfur combines with oxygen to form sulfur dioxide and sulfur trioxide. Sulfur will spontaneously ignite between 248°C and 266°C at atmospheric pressure in the presence of air and oxygen. Sulfur combines directly with all metals, except gold and platinum. The Chemical Abstracts Registry number for sulfur is 7704-34-9 and the EPA Shaughnessy number is 077501.

Regulatory Position for Products Containing Sulfur

Sulfur, as described in this Standard, may be registered for sale, distribution, reformulation, and use in the United States. Considering all information available to the Agency from the open literature and provided to the Agency as of December 1, 1982, the Agency finds that none of the risk criteria found in Section 162.11 (a) of Title 40 of the U.S. Code of Federal Regulations were met or exceeded for pesticide products containing sulfur.

A review of the data base indicates that the use of sulfur as a pesticide will not result in unreasonable adverse effects to man or the environment. Currently registered sulfur products may be reregistered subject to the conditions imposed by this standard. New products and new uses may be registered under this Standard and are subject to the same requirements.

Regulatory Rationale

Sulfur is a non-metallic element that has been known since very early times. Sulfur is federally registered as both a fungicide and an insecticide for use on a broad range of agricultural crops and ornamental plants. Sulfur products are registered for both domestic and nondomestic, terrestrial (food and nonfood), outdoor use. Additionally, there are two sulfur products,in the form of sulfur candles, that are currently registered for indoor use. These products are used as fumigants to control bed bugs. These products may be registered under this Standard.

No data gaps exist in the product chemistry data base. Some of the manufacturers of sulfur are Georgia Gulf Sulfur, Florida Agricultural Supply Company, Niagara Chemical Division (FMC Corporation), Bayer AG, and Excel Industries. Although none of the above mentioned manufacturers submitted any data regarding the manufacturing process of sulfur, basic manufacturing process data are available from the open literature. Additionally, the open literature describes many analytical methods which can be used in the identification and quantification of sulfur in formulations.

Most of the sulfur produced is 99.5% pure, with the remaining amount being carbonaceous impurities and moisture. Technical sulfur is considered a manufacturing-use product.

Data on the physical/chemical properties of technical sulfur depend on the manufacturing process. However, since sulfur is produced initially at a high degree of purity (99.5%), there should be little variance among the sulfur products. Physical/chemical properties data were extracted from the open literature.

Acute toxicity data indicate a low toxicity potential to humans. The oral LD_{50} in rats was determined to be greater than 5000 mg/kg, indicating toxicity category IV. The acute dermal LD_{50} in rabbits is determined to be greater than 2,000 mg/kg and no signs of systemic toxicity were found associated with this dose level.

The acute inhalation LC_{50} in rats was determined to be 9.23 mg/liter and no untoward reactions were observed. Subchronic inhalation exposure to sulfur in rats showed body weight depression, decreased blood sulfhydryl contents, decreased serum peroxidose levels, and increased serum albumin. In humans chronic inhalation exposure to sulfur is well documented in mine and refinery workers. Chronic bronchitis is generally found in those individuals as well as chronic sinusal effects and respiratory disturbances.

Optical application of sulfur to rabbits produced conjunctival redness and discharge. Epidemiologic studies with mine-workers who were exposed to sulfur dust and SO_2 during their life time revealed ocular disturbances as one of the principal toxicity signs.

There are no known risks of chronic, oncogenic, mutagenic, teratogenic, or reproductive hazards associated with sulfur.

The files of the Pesticide Incident Monitoring System (PIMS) contained records of 241 incidents of accidental exposure to sulfur. Of the 241 reported incidents, 175 involved human exposure to sulfur alone. Forty-eight (27%) of these incidents involving humans involved workers reentering treated areas. The majority of these incidents occurred in California. The primary route of exposure was dermal.

Additional data indicate that in 1980, the California Department of Food and Agriculture (CDFA) received 2,436 reports of pesticide-related illness submitted through county health officers (Maddy, 1980, GS0031-0001). Approximately 175 reports involving exposure to sulfur, of which 106 incidents were field workers exposed to pesticide residues. Eighty-seven of the 106 incidents involved skin irritation, 17 involved eye irritation, and 2 were systemic effects. In 1981, approximately 127 reports involving exposure to sulfur were reported to CDFA. Ninety-seven incidents (79%) involved field workers exposed to sulfur as follows: 83 reports of skin irritation, 12 reports of eye irritation, 1 report of eye and skin irritation, and 1 report of systemic illness. Some of these reports may have been included in the PIMS data base but it is not possible to determine if any of the incidents are included in both the PIMS data and in the California report.

Reentry intervals are required to support the registration of all products for which the Agency has determined that a reentry hazard exists for persons reentering treated sites. There are records of reported cases of reentry worker injury, primarily skin and eye irritation. The Agency recognizes the California State reentry interval of 24 hours for the use of sulfur on agricultural crops (California Administrative Code, January 4, 1979, Article 23, 2479 (H), Field Worker Safety). Registrants of sulfur products have the option of proposing an acceptable reentry interval based on one of the following: the longest, most restrictive existing interval for sulfur; data on dissipation of foliar residues (decline curve), on human exposure to those residues, and on toxicity of sulfur; determination of that time beyond which there are no detectable, dislodgeable residues remaining in the worker environment.

The available data are insufficient to allow a complete assessment of the environmental fate of elemental sulfur when used as a pesticide. Sulfur is a component of the environment, and there is a natural cycle of oxidation and reduction reactions which transforms sulfur into both organic and inorganic products. Sulfur in the form of sulfate (HSO_4^-) constitutes about 0.1% of the United States soils. Elemental sulfur is slowly converted to sulfate in soil by the action of autotrophic bacteria. The sulfate anion has been shown to leach through soil at a slow rate. With the exception of reentry data, the testing requirements for environmental fate have been waived since sulfur is a natural component of the environment and, in addition has non-pesticidal applications.

Available data indicate that little hazard to non-target organisms is expected from the use of sulfur. Data show that sulfur is practically non-toxic to birds, fish, and aquatic invertebrates. The 96-hour LC_{50} values for two fish species, bluegill sunfish and rainbow trout, are >180 ppm. The 48-hour LC_{50} for Daphnia magna and the 96-hour LC_{50} for mysid shrimp is reported to be >5000 ppm and between 646-839 ppm, respectively.

Two beneficial insect studies demonstrated that sulfur is low in toxicity to the honey bee through both contact and ingestion.

No residue chemistry data on metabolism, analytical methodology, and the level of residues on the raw agricultural commodities which may result from the use of sulfur are available. Based on the toxicological data review completed for the development of this Standard, residue chemistry data are still not required.

Criteria for Registration Under this Standard

To be subject to this Standard, sulfur products must meet the following conditions:

1. contain sulfur as an active ingredient;
2. be within acceptable standards of product composition;
3. be within acceptable acute toxicity limits;
4. be labeled for acceptable end-uses; and
5. bear required labeling.

Manufacturing-use sulfur products must bear label directions for formulation into acceptable end-uses.

The applicant for registration or reregistration of sulfur products subject to the Standard must comply with all terms and conditions described in this Standard, including commitment to fill data gaps on a time schedule specified by the Agency and, when applicable, offer to pay compensation to the extent required by 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, 7 U.S.C. 136 (c)(1)(D) and 136 (c)(2)(D). As discussed in Chapter 1, applicants for the registration of sulfur products under this Standard must contact the Agency for specific instructions, including updated information on data requirements and companies whose data must be cited and to whom compensation must be offered.

A. Manufacturing-use Sulfur

1. Acceptable Ranges and Limits

a. Product Composition Standards

There are five currently registered manufacturing-use sulfur products: three technical sulfur products (95% and 99.5%), and two formulation intermediate products (93%). To be covered under this Standard, manufacturing-use sulfur products must contain sulfur as the sole active ingredient or in combination with other active ingredients. Manufacturing-use sulfur products with any percentage of active ingredient with appropriate certification of limits are acceptable under this Standard.

b. Acute Toxicity Limits

The Agency will consider registration of manufacturing-use sulfur products which have established acute toxicity category I-IV ratings for each of the following effects:

Acute Oral Toxicity
Acute Dermal Toxicity
Acute Inhalation Toxicity
Primary Eye Irritation
Primary Dermal Irritation

c. Use Patterns

To be covered under this Standard, manufacturing-use sulfur products must be labeled for formulation into end-use pesticides which are intended for indoor/outdoor, domestic/nondomestic, terrestrial/aquatic (food or non-food uses), or other uses accepted by the Agency. There are two products, in the form of sulfur candles, that are currently registered for indoor use as fumigants to control bed bugs and can be registered under this Standard.

2. Required Labeling

All manufacturing-use sulfur products must bear appropriate labeling as specified in 40 CFR 162.10.

3. Tolerance Reassessment

Sulfur is recognized as safe for use as a pesticide and, is exempted from tolerances. Information from Canada indicates that the use of sulfur on raw agricultural commodities and food or feed items in that country is exempt from the requirements of a tolerance and that the use of sulfur according to good agricultural practices is recognized as safe. No Maximum Residue Levels (MRL's) for residues from the use of sulfur on agricultural commodities are indicated by Codex Alimentaris.

Chapter III

Data Requirements and Data Gaps

Manufacturing-Use Sulfur

Table A entitled, Generic Data Requirements includes those data that pertain to the properties or effects of sulfur as an active ingredient. Thus, these data are relevant to an evaluation of the risks and benefits of all products containing sulfur. Providing data to fill indicated gaps is the primary responsibility of the manufacturing-use product registrant(s). Registrants of end-use products which are not exempted by FIFRA Section 3(c)(2)(D) are also responsible for the submission of these data. Applicants for the registration or reregistration of manufacturing-use sulfur products must acknowledge reliance on existing data which fill indicated data requirements under FIFRA 3(c)(1)(D). These data are listed under the column entitled Bibliographic Citation in this table. All data requirements are required for all currently registered use patterns unless a footnote to the table specifies otherwise.

Table B, entitled Product-Specific Data Requirements for Sulfur Manufacturing-Use Products ,includes those data that relate only to the properties or effects of a product with a specific composition. Thus, these data are required of each product to characterize the product's particular composition and physical/chemical properties, and acute toxicity. Providing data to fulfill these data requirements for a particular product is the responsibility of each applicant for the registration or reregistration of a manufacturing-use sulfur product. If the Agency has in its possession product-specific data which fulfill a data requirement for a particular product, this is indicated in the guidance package accompanying this Standard.

Applicants for the registration of new manufacturing-use sulfur products must submit all required product specific data or establish that the proposed product is substantially similar to another product for which the Agency has received acceptable product specific data.

If the Agency has determined that one or more existing manufacturing-use sulfur products are substantially similar, then this, too, is indicated. Product specific data need not be acknowledged under FIFRA 3(c)(1)(D) unless the Agency or a registrant has established that a product is substantially similar to another product for which the Agency has received acceptable product specific data. If this should occur, the registrant(s) of the former product(s) is required to acknowledge reliance on these data.

TABLE A

Generic Data Requirements for Sulfur

Guidelines Citation	Name of Test	Are Data Required?	Does EPA Have Data to Partially or Totally Satisfy Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, deadline for submission
Product Chemistry:					
163.61-3(b)	Identification	Yes	Yes	1/	No
163.61-8(1)	Color	Yes	Yes	Meyer, 1976, 05012688	No
163.61-8(2)(c)	Odor	Yes	Yes	Murthy, 1974, 05013038	No
163.61-8(3)	Melting Point	Yes	Yes	Donohue, 1961, 05015875	No
163.61-8(4)(c)	Solubility	Yes	Yes	Tuller, 1970, 05015159	No
163.61-8(5)	Stability	Yes	Yes	Tuller, 1970, 05015159	No
163.61-8(6)	Octanol/Water Partition coefficient	No			
163.61-8(7)	Physical State	Yes	Yes	Donohue, 1961, 05015875	No

1/ Data taken from internal files and chemical handbooks.

TABLE A

Generic Data Requirements for Sulfur

Guidelines Citation	Name of Test	Are Data Required?	Does EPA Have Data to Partially or Totally Satisfy Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, deadline for submission
Product Chemistry:					
163.61-8(8)	Density or Specific Gravity	Yes	Yes	West, 1950, 05011811	No
163.61-8(9)	Boiling Point	No			
163.61-8(10)	Vapor Pressure	Yes	Yes	Gruener, 1907, 05011817	No
163.61-8(11)	pH	No			

Table A

Generic Data Requirements for Sulfur

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
Environmental Fate:						
163.161-1	Hydrolysis	Yes	Radiolabeled analytical grade or nonlabeled technical grade	No	-	No[1/]
163.161-2	Photodegradation in water	Yes	Radiolabeled analytical grade or nonlabeled technical grade	No	-	No[1/]
163.161-3	Photodegradation in soil	Yes	Radiolabeled analytical grade or nonlabeled technical grade	No	-	No[1/]
161.161-4	Photodegradation in air	Yes	Radiolabeled analytical grade or nonlabeled technical grade	No	-	No[1/]

1/ Since sulfur is a natural component of the environment and, in addition, has non-pesticidal applications, the testing requirements for environmental fate have been waived.

Table A

Generic Data Requirements for Sulfur

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
Environmental Fate:						
163.162-1	Aerobic Soil	Yes	Radiolabeled analytical grade or nonlabeled technical grade	No	-	No[1/]
163.162-2	Anaerobic Soil	Yes	Radiolabeled analytical grade or nonlabeled technical grade	No	-	No[1/]
163.162-3	Anaerobic Aquatic	No[2]				
163.162-4	Aerobic Aquatic	No[2/]				

1/ Since sulfur is a natural component of the environment and, in addition, has non-pesticidal applications, the testing requirements for environmental fate have been waived.

2/ Data on the anaerobic aquatic or aerobic aquatic metabolism are not required because the use pattern indicates that introduction of sulfur into an aquatic environment or forest ecosystem would not occur.

Table A

Generic Data Requirements for Sulfur

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
Environmental Fate:						
163.62-8(f)	Effects of microbes on pesticides	Reserved[3/]				3/
163.62-8(f)	Effects of pesticides on microbes	Reserved[3/]		Partial	Toth and Tomasovicova, 1979, 05018847; Badway, 1978, 05011773	3/
163.62-8(g)	Activated sludge metabolism	Reserved[4/]				
163.163-1	Leaching	Yes	Radiolabeled analytical grade or nonlabeled technical grade	Yes	Jones, 1979, 050118847	No
163.163-2	Laboratory volatility	Yes	Typical end use product of a major formulation category	No	-	No[5/]
163.163-3	Field volatility	Yes[1/]	Typical end-use product of a major formulation category	No	-	No[5/]

3/ The requirement for the submission of any additional microbiological data is currently being reserved pending the review and modification of testing protocols.

4/ The requirement for the submission of these data is currently being reserved pending the review and modification of the testing protocols.

5/ The requirement for the submission of laboratory volatility data for sulfur has been waived.

Table A

Generic Data Requirements for Sulfur

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
Environmental Fate:						
163.164-1	Field Dissipation Terrestrial	Yes	Representative formulation from major formulation categories	No	-	No[1/]
163.164-2	Field Dissipation Aquatic and Aquatic Impact	No[6/]				
163.164-3	Dissipation-Forestry	No[7/]				
163.164-4	Dissipation-Combination and Tank Mixes	No				
163.164-5	Dissipation-Long Term Studies	No				

1/ Since sulfur is a natural component of the environment and, in addition, has non-pesticidal applications, the testing requirements for environmental fate have been waived.

6/ Data on the aquatic field dissipation of sulfur are not required because the use pattern indicates that introduction of sulfur into an aquatic environment would not occur.

7/ Data on the dissipation of sulfur in forests are not required because the use patttern indicates that introduction of sulfur into a forest environment would not occur.

Table A
Generic Data Requirements for Sulfur

Guideline Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
Environmental Fate:						
163.165-1	Confined Accumulation - Rotational Crops	No				
163.165-2	Field Accumulation - Rotational Crops	No				
163.165-3	Accumulation - Irrigated Crops	No				
163.165-4	Laboratory Studies - Fish	No[8/]				
163.165-5	Field Accumulation Aquatic Non-target	No				
	Reentry	Yes[9/]	Representative Formulation Types	No	-	Yes: 24 months

8/ The requirement for submission of this data is waived because sulfur is not expected to accumulate in fish.
9/ For each crop, the registrant is required to propose an acceptable reentry interval based on one of the following: (a) the longest (most restrictive existing interval for sulfur is the 24-hour interval established by the State of California); or (b) data on dissipation of foliar residues (decline curve), on human exposure to those residues, and on toxicity of sulfur; or (c) determination of the time beyond which there are no detectable, dislodgeable residues remaining in the worker environment.

Table A

Generic Data Requirements for Sulfur

Guideline Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
Toxicology						
163.81-1	Acute Oral Toxicity	Yes	Technical Grade	Yes	Doull, 1977, 00009932	No
163.81-2	Acute Dermal Toxicity	Yes	Technical Grade	Yes	Baker, 1976, 00009951	No
163.81-7	Acute Neurotoxicity	No				
163.82-1	Subchronic Oral Toxicity	Yes	Technical Grade	Yes	Groves, 1946, 05012348	No
163.82-2	Subchronic 21-day Dermal Toxicity	No				
163.82-3	Subchronic 90-day Dermal Toxicity	No				
163.82-4	Subchronic Inhalation Toxicity	No				

Table A
Generic Data Requirements for Sulfur

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
Toxicology						
163.83-1	Chronic Feeding	No	Technical Grade	Yes	Anon, 1977, 05011353	No
163.83-2	Oncogenicity	No				
163.83-3	Teratogenicity	No				
163.83-4	Reproduction	No	Technical Grade	Yes	Nagy, 1975, 05011624	No
163.84-2 through 4	Mutagenicity	No				
163.85-1	Metabolism	No				

Table A

Generic Data Requirements for Sulfur

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
Residue Chemistry:						
	Metabolism in Plants	No				
	Metabolism in Animals	No				
	Analytical Methods	No				
	Residue Data: Crops	No				
	Residue Data: Meat and Milk	No				
	Storage Stability	No				

Table A

Generic Data Requirements for Sulfur

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
Ecological Effects						
163.71-1	Avian Single-Dose Oral LD_{50}	No[1/]				
163.71-2	Avian Dietary LC_{50}	Yes - Outdoor Uses	Technical Grade	Yes	Fink, 1982, GS0031-0003	No[1/]
163.71-3	Wild Mammal Toxicity	No				
163.71-4	Avian Reproduction	No				
163.71-5	Simulated and Actual Field Testing for Mammals and Birds	No				

1/ Since sulfur is a required nutrient for all organisms and no avian hazards from the use of sulfur are known, the requirements for the submission of further avian data are waived.

Table A
Generic Data Requirements for Sulfur

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
Ecological Effects:						
163.72-1	Fish Acute LC_{50}	Yes - Outdoor Uses	Technical Grade	Yes	US EPA, 1975, GS0031-0004 US EPA, 1976, GS0031-0005	No
163.72-2	Aquatic Invertebrate Acute LC_{50}	Yes - Outdoor Uses	Technical Grade	Yes	Borthwich and Stanley, 1982, 1982, GS0031-0002	No
163.72-3	Acute Toxicity to Estuarine and Marine Organisms	Yes - Citrus Cotton Soybean Uses	Technical Grade	Yes	Borthwich and Stanley, 1982, GS0031-0002	No 2/
163.72-4	Fish Early Life - Aquatic Invertebrate Life-Cycle	No				

2/ Available aquatic organism indicates that sulfur is practically non-toxic, no further data are required.

Table A
Generic Data Requirements for Sulfur

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
Ecological Effects:						
163.72-5	Fish Life-Cycle	No				
163.72-6	Aquatic Organism Accumulation	No				
163.72-7	Simulated or Actual Field Testing for Aquatic Organisms	No				
163.70-1(d)	Reptile and Amphibian LC_{50}	No				

Table B

Product-Specific Data Requirements for Manufacturing-Use Sulfur Products

Guidelines Citation	Name of Test	Are Data Required?	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
Product Chemistry:					
163.61-3	Product Identity and Disclosure of Ingredients	Yes	Yes	1/	No
163.61-4	Description of Manufacturing Process	Yes	Yes	Tuller, 1970, 05015159 Lowell, 1976, 05010579 Young, 1941, 05011669; Streeter, 1930, 05011675	No
163.61-5	Discussion of Formation of Unint. Ingredients	Yes	Yes	Groves, 1942, 05016152	No
163.61-6	Declaration and Certification of Ingredient Limits	Yes	Yes	2/	No

1/ Data taken from internal files and chemical handbooks.
2/ Data taken from confidential statement for formula.

Table B

Product-Specific Data Requirements for Manufacturing-Use Sulfur Products

Guidelines Citation	Name of Test	Are Data Required?	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
Product Chemistry:					
163.61-7	Product Analytical Methods and Data	Yes	Yes	Richard, 1977, 05011812	No
163.61-8(c)(7)	Physical State	Yes	Yes	Donohue, 1961, 05015875	No
163.61-8(8)	Density or Specific Gravity	Yes	Yes	West, 1950, 05011811	No
163.61-8(9)	Boiling Point	No			

Table B

Product-Specific Data Requirements for Manufacturing-Use Sulfur Products

Guidelines Citation	Name of Test	Are Data Required?	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
Product Chemistry:					
163.61-8(c)(11)	pH	No			
163.61-8(c)(12)	Storage Stability	Yes	Yes	3/	No
163.61-8(c)(13)	Flammability	No			
163.61-8(c)(14)	Oxidizing or Reducing Action	Yes	Yes	3/	No
163.61-8(c)(15)	Explosiveness	Yes	Yes	West, 1950, 05011811	No
163.61-8(c)(16)	Miscibility	No			
163.61-8(c)(17)	Viscosity	No			
163.61-8(c)(18)	Corrosion Characteristics	Yes	Yes	Tuller, 1970, 05015159	No
163.61-8(c)(19)	Dielectric Breakdown Voltage	No			

3/ Data taken from EPA files and handbooks.
4/ These data are not required since usage indicates that sulfur is not used around powerlines and transformer stations.

Table B

Product-Specific Data Requirements for Manufacturing-Use Sulfur Products

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
Toxicology						
163.81-1	Acute Oral Toxicity	Yes	MUP	Yes	Doull, 1977, 00009932 Baker, 1976, 00009951 Rittenhause, 1975, 00009812	No
163.81-2	Acute Dermal Toxicity	Yes	MUP	Yes	Baker, 1976, 00009951	No
163.81-3	Acute Inhalation Toxicity	Yes	MUP	Yes	Rhudy, 1976, 00009952	No
163.81-4	Primary Eye Irritation	Yes	MUP	Yes	Rittenhause, 1975, 00009812	No
163.81-5	Primary Dermal Irritation	Yes	MUP	Yes	Baker, 1976, 00009951, 00009932	No
163.81-6	Dermal Sensitization	Yes	MUP	Yes	Basch, 1926, 05012779	No

Chapter IV

Product Chemistry

Introduction

FIFRA 3(c)(2)(A) requires the Agency to establish guidelines for registering pesticides in the United States. The EPA requires registrants to provide quantitative data on all active and added inert ingredients, and on those impurities, which are equal to or greater than 0.1% of the product by weight.

To establish the composition of products proposed for registration, the Agency requires data and information not only on the manufacturing and formulation processes but also a discussion on the formation of manufacturing impurities and other product ingredients, intentional and unintentional. Further, to assure that the composition of the product as marketed will not vary from the composition evaluated at the time of registration, applicants are required to submit a statement certifying upper and lower composition limits for the added ingredients, and upper limits for some unintentional ingredients. Subpart D of the Proposed Guidelines (43 FR 29696, July 10, 1978) suggests specific precision limits for ingredients based on the percentage of ingredient and the standard deviation of the analytical method.

In addition to the data on product composition, the Agency guidelines also require data on the physical and chemical properties of both the pesticide active ingredient and formulations. For example, data are needed concerning the identity and physical state of the active ingredient such as melting and boiling point data, ambient vapor pressure and solubility. Data are also required on the properties of the formulated product to establish labeling precautions (e.g., flammability, corrosiveness, or storage stability). The Agency uses these data to characterize each pesticide and to determine its environmental and health hazards.

Product Chemistry: Manufacturing-use Sulfur

Product Chemistry Profile

Sulfur is the common name for this chemical although the American National Standards Institute has no official designation. Other names also used are sulphur and brimstone.

Technical sulfur is a yellow, odorless, solid consisting of two allotropic forms: rhombic with a melting point of 112.8°C and monoclinic with a melting point of 119°C. Sulfur is practically insoluble in water and slightly soluble in ethanol and ether. The crystalline forms of sulfur are soluble in carbon disulfide whereas the amorphous forms are not.

Technical sulfur is intended only for re-formulation into an end-use pesticide and, therefore, is considered a "manufacturing-use" product.

al Discussions

cal Identity

ur, a non-metallic element that has been known from very early times, is official common name for this compound. The chemical formula is S and the ic weight is 32.06. The Chemical Abstracts Registry number for sulfur 704-34-9 and the EPA Shaughnessy number is 077501.

facturing Processes

e of the manufacturers of sulfur for pesticide use are Georgia Gulf phur, Florida Agricultural Supply Company, Niagara Chemical Division (FMC poration), Bayer AG, and Excel Industries. None of the above mentioned ufacturers submitted any data regarding the manufacturing process of sulfur.

wever, additional data on the manufacturing process are not needed because sic manufacturing data are available from the open literature. In the United ates, sulfur is mostly produced around the Gulf of Mexico, primarily in xas, Louisiana, and Florida. The sulfur is either mined from sulfur posits or recovered as a side product in the distillation of crude petroleum l and the cleanup of natural gas (methane). When sulfur is mined, super- eated water is pumped into a sulfur deposit and the melted sulfur is ecovered by forcing it to the surface with compressed air. This procedure is nown as the Frasch process (Tuller, 1970, 05015159). The production of ulfur from crude petroleum or natural gas can include one of fourteen ifferent chemical reactions (Lowell, 1976, 05010579).

verall, most of the sulfur produced is 99.5% pure with the remaining amount being carbonaceous impurities and moisture. For agricultural use it is very important that the particle size of sulfur be controlled; depending upon its use as an insecticide, miticide, or fungicide, the particle size should range between 5 and 200 microns (Young, 1941, 05015676; Streeter, 1930, 05015160; Smith, 1930, 05011669; 05011675).

Formation of Unintentional Ingredients

Detailed information on unintentional impurities, which may be present in technical sulfur used for agricultural pesticidal purposes, was not submitted by the manufacturers of record.

Data in the literature indicate that technical sulfur usually is manufactured at 99.5% purity with the remainder consisting of carbonaceous material and moisture (Groves, 1942, 05016152). No additional information is required.

There are two formulation intermediate products (93% A.I.) manufactured by the Thompson-Hayward Chemical Company. Information on unintentional impurities which may be present in these formulations is presented in the Confidential Appendix to this Standard.

Percentages of Active Ingredient in Pesticide Products

Confidential statements of formula for technical sulfur and manufacturing-use sulfur have been submitted and are included in the Confidential Appendix to this Standard.

Labels for technical sulfur products produced by Florida Agricultural Supply Company and Niagara Chemical Division, FMC Corporation, claim the products contain 99.5% sulfur. Technical sulfur is considered a manufacturing-use product.

Product Analytical Methods and Data

The EPA Manual of Chemical Methods for Pesticides and Devices reports three methods for the analysis of sulfur in various formulations containing sulfur.

In addition, the open literature contains many methods using various modern instrumental analytical techniques which can be used in the identification and quantification of sulfur in formulations (Richard, 1977, 05011812; Eli Lilly and Co., 1977, 00020745; Meyers, 1976, 00009917; Cassidy, 1976, 05010994). No additional data are required.

Physical and Chemical Properties

The physical/chemical properties of technical sulfur depend primarily on the manufacturing process. Since sulfur is produced initially at a high degree of purity (99.5%), there should be little variance in the physical/chemical properties as a function of a large number of producers. No physical/chemical properties data were submitted by the registered manufacturers, and accordingly the data reflected here are extracted from the open literature.

Color	Yellow (Meyer, 1976, 05012688)
Odor	Odorless (Murthy, 1974, 05013038)
Physical State	Sulfur exists in two allotropic forms
Melting Point	112.8°C rhombic crystals; 119°C monoclinic (Donohue, 1961, 05015875)
Density	Density of diatomic sulfur at 116 atm. and 1010°C is 0.393 gr/cc; (West, 1950, 05011811)
Solubility	Practically insoluble in water; Slightly soluble in ethanol and ether; the crystalline forms are soluble in CS_2 whereas the amorphous forms are not; (Tuller, 1970, 05015159)

Vapor Pressure	Vapor pressure is 0.0070 mmHg at a mean barometric pressure of 740.7 mmHg and a temperature of 99.3°C; (Gruener, 1907, 05011817)
Stability	Amorphous sulfur is not stable at a temperature below 160°C. Depending on the ambient temperature, it either changes to orthorhombic or monoclinic crystalline sulfur. (Tuller, 1970, 05015159)
Oxidizing and Reducing Action	At room temperature, sulfur is not chemically active; when heated, sulfur combines with oxygen to form sulfur dioxide and sulfur trioxide.
Explosiveness	Sulfur will spontaneously ignite between 248°C and 266°C at atmospheric pressure in the presence of air and oxygen. (West, 1950, 05011811) A sulfur dust mixture with a concentration ranging from 0.035 oz/cu ft – 1.4 oz/cu ft of air will be ignited by a flame or spark.
Storage Stability	Sulfur is considered to be a stable compound (Tuller, 1970, 05015159)
Corrosion Characteristics	Sulfur combines directly with all metals, except gold and platinum (Tuller, 1970, 05015159).

Additionally, data concerning the ultraviolet band of sulfur and the infrared spectrum of sulfur are available (Gilles, 1929, 05016368; Taylor, 1929, 05011812).

Chapter V

Environmental Fate

Use Profile

Elemental sulfur is federally registered as both a fungicide and as an insecticide. As a fungicide, sulfur is registered for use on a broad range of agricultural crops and ornamentals to control powdery mildew, as well as numerous other foliar diseases and fruit rots. As an insecticide, sulfur is primarily used to control mites. It is estimated that between 135-190 million pounds of sulfur are used annually as a pesticide. The major high usage sites include: grapes, peaches, sugarbeets, and citrus.

At present, there are 148 federally registered products and 98 state registration containing sulfur as a single active ingredient fungicide. As an insecticide, there are 129 federally registered products and 70 state registrations. Sulfur is formulated into dusts (20-99.8% A.I.), wettable powders (30-97% A.I.), wettable powder/dusts (90-98.5% A.I.), and flowable concentrates (6 and 8 lb/gal). Insecticidal formulations also include an ointment for topical use, and a sulfur candle for use as a space fumigant.

Environmental Fate Profile

The data available are insufficient to allow a complete assessment of the environmental fate of elemental sulfur when applied as a pesticide. Sulfur is a component of the environment, and there is a natural cycle of oxidation and reduction reactions which transforms sulfur into both organic and inorganic products. Sulfur in the form of sulfate (HSO_4^-) constitutes about 0.1% of U.S. soils. Elemental sulfur is slowly converted to sulfate in soil by the action of autotrophic bacteria. Sulfur is also used non-pesticidally as a soil amendment to correct sulfur deficiencies and to reduce soil pH; conversion to sulfate follows soil application and is necessary to achieve these results. The sulfate anion has been shown to leach through soil at a slow rate.

Since sulfur is a natural component of the environment and, in addition, has non-pesticidal applications, the testing requirements for environmental fate have been waived, with the exception of testing relating to reentry considerations. With respect to the reentry considerations, the registrant is required to propose an acceptable reentry interval based on one of the following: the longest, most restricting existing interval for sulfur; data on dissipation of foliar residues on human exposure to those residues, and on toxicity of sulfur; determination of that time beyond which there are no detectable, dislodgeable residues remaining in the worker environment.

One environmental fate study was reviewed and determined to be valid. The results of the study indicate that elemental sulfur leaches in soil as sulfate. About 3-6% of the sulfur (formulation and purity unspecified) applied at 56 kg/Ha leached through lysimeters of loam soil (soil depth unspecified) as a result of 40 inches of rain over a six-month period. After two years, 23-29% of the applied sulfur had leached.

Topical Discussions

Degradation

No data are available on the hydrolysis of sulfur or the photodegradation of sulfur in water, soil, or air. The requirements for the submission of these data are waived.

Metabolism

Data on metabolism are required to determine the nature and availability of pesticide residues to rotational crops and to help in the assessment of potential disposal and reentry hazards.

No data are available on the aerobic or anaerobic soil metabolism of sulfur. The requirements for the submission of these data are waived.

Data on the anaerobic aquatic or aerobic aquatic metabolism are not required because the use pattern indicates that introduction of sulfur into an aquatic environment or forest ecosystem would not occur.

Microbiological

Two studies on the effects of sulfur on microbes were reviewed and determined to be valid. Badway (1978, 05011773) found that the total number of soil microbes was unaffected by field applications of sulfur (formulation and purity unspecified) at rates as high as 850 lb/A up to 5 months after treatment. Autotrophic sulfur-oxidizing bacteria were stimulated up to 40-fold by sulfur application. Toth and Tomasovicova (1979, 05018847) determined that sulfur (Sulikol colloidal sulfur, purity unspecified) at 1 ppm or less caused slight to moderate, yet temporary, reductions in numbers of the protozoan Tetrahymena pyriformis. Sulfur at 10 ppm killed all the cells of the protozoan. The LD_{50} at 2 days was calculated as 0.16 ppm.

The requirement for the submission of any additional microbiological data is currently being reserved pending the review and modification of testing protocols.

Activated Sludge

No data are available to assess the activated sludge metabolism of sulfur. The requirement for the submission of these data is currently being reserved pending the review and modification of the testing protocols.

Mobility

The movement of pesticide residues by means of leaching through soil may cause contamination of food, result in a loss of usable land and water resources to man due to contamination of groundwater supplies, or cause habitat loss to wildlife. Therefore, studies are required to ascertain the extent of pesticide leaching through soil, which, in turn, provides a basis for assessing the mobility potential of a pesticide.

Leaching

One leaching study was reviewed and found to be valid. Jones et al., (1971, 05010904) determined that elemental sulfur leaches in soil as SO_4-S. About 3-6% of the sulfur (formulation and purity unspecified) applied at 56 kg/ha leached through lysimeters of loam soil (soil depth unspecified) as a result of 40 inches of rain over 6-month period. After 2 years, 23-29% of the applied sulfur had leached.

This study partially fulfills the requirement for leaching data for sulfur. The requirement for further testing is waived.

Laboratory Volatility

A laboratory volatility study will be required on a case-by-case basis to support the registration of each manufacturing-use product which legally could be used to make end-use products intended for commercial greenhouse, orchard, or field and vegetable crop uses that involve significant inhalation exposure to workers.

No data on the volatility of sulfur under laboratory conditions are available. The requirement for the submission of laboratory volatility data for sulfur has been waived.

Field Volatility

A volatility study conducted on-site in a commercial greenhouse and/or in the field will be required on a case-by-case basis only for those pesticides that the Agency considers pose a potentially significant inhalation exposure to workers and that there is a significant rate of volatilization from soil.

No data on the field volatility of sulfur are available. The requirement for the submission of field volatility data for sulfur has been waived.

Dissipation

Field Dissipation-Terrestrial

No data are available to assess the terrestrial field dissipation of sulfur. The requirement for the submission of field dissipation (terrestrial) data has been waived.

Field Dissipation-Aquatic and Aquatic Impact

Data on the aquatic field dissipation of sulfur are not required because the use pattern indicates that introduction of sulfur into an aquatic environment would not occur.

Dissipation-Forestry

Data on the dissipation of sulfur in forests are not required because the use pattern indicates that introduction of sulfur into a forest environment would not occur.

Dissipation-Combinations and Tank Mixes

Data requirements for combinations and tank mixes containing sulfur are not cited here because this standard deals only with the single active ingredient.

Dissipation-Long Term

A long-term soil dissipation study will be required to support the registration of manufacturing-use products that legally could be used to make end-use products that have been shown not to readily dissipate in a soil environment. The requirement for the submission of long-term soil dissipation data are waived.

Accumulation

Confined Accumulation-Rotational Crops

Confined accumulation studies on rotational crops are required to support the registration of each manufacturing-use product which legally could be used to make end-use products intended for field or vegetable crop use, aquatic crop use, or use on any other site on which it is reasonably foreseeable that any food or feed crop may be produced after application of a pesticide. This data requirement is waived for sulfur.

Field Accumulation-Rotational Crops

A field accumulation study to determine the uptake of soil residues by rotational crops is required when (1) the confined accumulation study identifies the ^{14}C residues in the crop as either parent compound, closely-related degradates, metabolites, and/or their conjugates or (2) a subsequent crop is treated with the same active ingredient as the initial crop. This data requirement is waived for sulfur.

Accumulation-Irrigated Crops

Data on the accumulation of sulfur in irrigated crops are not required because the use pattern indicates that crops are not irrigated with sulfur-treated water and that introduction of sulfur into the aquatic environment would not occur.

Laboratory Studies-Fish

A fish accumulation study is required to support the registration of each end-use product intended for outdoor use (except domestic outdoor and greenhouse uses), or aquatic impact use resulting in direct discharge into aquatic environments, and for each manufacturing-use product that legally could be used to produce such a product, except when the criteria below are satisfied.

Fish accumulation data will not normally be required in situations where the registrant can offer acceptable evidence showing that the active ingredient and/or its principal degradation product(s):

Will not reach water, or
Will not persist in water (i.e., a half-life of approximately 4 days or less) and has properties suggesting:
- A relatively low potential for accumulation in fish (i.e., an octanol/water partition coefficient less than 1000) or
- A lack of accumulation in the organs and tissues of mammals or birds.

The requirement for submission of this data is waived because sulfur is not expected to accumulate in fish.

Fish Accumulation-Aquatic Non-Target

Field accumulation studies in aquatic non-target organisms are required to support the registration of each end-use product:

- Which is intended for forestry use, aquatic non-crop use, or aquatic impact use that results in direct discharges;
- For which data from a laboratory fish accumulation study are required by Section 163.165-4; and
- For which no tolerance or action level for fish has been granted.

Such studies are also required to support the registration of each manufacturing-use product which legally could be used to make such an end-use product. No data are required for sulfur because it would not be expected to accumulate in fish.

Reentry

Reentry intervals are required to support the registration of all products for which the Agency has determined that a reentry hazard exists for persons reentering treated sites. There are records of reported cases of reentry worker injury, primarily skin and eye irritation.

The California State reentry interval is 24 hours for the use of sulfur on agricultural crops (California Administrative Code, January 4, 1979, Article 23, 2479 (H), Field Worker Safety). For each crop, the registrant is required to propose an acceptable reentry interval based on one of the following:

(a) the longest (most restrictive) existing interval for sulfur; or

(b) data on dissipation of foliar residues (decline curve) on human exposure to those residues, and on toxicity of sulfur; or

(c) determination of that time beyond which there are no detectable, dislodgeable residues remaining in the worker environment.

Chapter VI

Toxicology

Toxicology Profile

Acute Toxicity

Acute toxicity data for sulfur are available and are summarized in the table below:

Table 1

Acute Toxicity Data for Sulfur

Type of Study	Test Substance	Results	Toxicity Category	Reference
Acute Oral (Male, Rat)	Precipitated Sulfur	LD_{50} > 3000 mg/kg;	III	Doull, 1977, 00009932
Acute Oral (Male and Female, Rat)	Sulfur (52% w/w)	LD_{50} > 5000 mg/kg	IV	Baker, 1976, 000009951
Acute Dermal (Male and Female, Rabbit)	Sulfur (52% w/w)	LD_{50} < 2000 mg/kg	III-IV	Baker, 1976, 00009951
Acute Inhalation (Male and Female, Rat)	Flowable sulfur (52% w/w)	4-hour LC_{50} > 9.23 mg/liter	III	Rhudy, 1976, 00009952
Acute Dermal Irritation	Flowable Sulfur	Sulfur produced mild irritation at 72 hours; this irritation was characterized by erythema; reddish colored skin and barely perceptible edema at 24 hours;	III	Baker, 1976, 00009951

Subchronic and Chronic Toxicity

Subchronic inhalation exposure to sulfur in rats showed body weight depression, decreased blood sulfhydryl contents, decreased serum peroxidase levels, and increased serum albumin. No significant changes in the blood morphology, blood sugar level, or behavioral changes were observed in these animals (Brilinskii, 1965, 05016307). In humans, chronic inhalation exposure to sulfur is well documented in mine and refinery workers and chronic bronchitis is generally found in those individuals in addition to chronic sinusal effects and respiratory disturbances.

Chronic dermal application of elemental sulfur for 1 year in mice (50 mg/twice weekly) indicates that elemental sulfur is not carcinogenic by this route of administration and in this species (Anon., 19??, 05011353).

Sulfur has been shown to be non-mutagenic in microorganisms when incubated without a metabolic activating system.

Accident Reports

The files of the Pesticide Incident Monitoring System (PIMS) contained records of 241 incidents of accidental exposure to sulfur. Of the 241 reported incidents, 175 involved human exposure to sulfur alone. Forty-eight (27%) of these incidents involving humans involved workers reentering treated areas. The majority of these incidents occurred in California. The primary route of exposure was dermal.

Additional data indicate that in 1980 and 1981, the California Department of Food and Agriculture received 3,529 reports of pesticide-related illness submitted through county health officers (Maddy, 1980, GS0031-0001). Approximately 302 reports involving exposure to pesticide residues. Of the 203 incidents were field workers exposed to pesticide residues. Of the 203 incidents, 170 involved skin irritation, 29 involved eye irritation, and 3 involved systemic effects. Some of these reports may have been included in the PIMS data base but it is not possible to determine if any of the incidents are included in both the PIMS data and in the California report.

Chapter VII

Residue Chemistry

Residue Chemistry Profile: Manufacturing-use Sulfur

Between 135-190 million pounds of sulfur are used each year in the United States in the treatment of grapes, peaches, sugar beets, oranges, grapefruit, potatoes, pecans, soybeans, and various other agricultural commodities. As a result of the Congressional Pesticide Residue-Spray Hearings in 1950, it was concluded that the use of sulfur is generally recognized as safe when applied to crops in accordance with good agricultural practices (CFR 40 Chapter 1, Section 180.2).

As a result of the outcome of these hearings, no residue chemistry data on metabolism, analytical methodology, and levels of residues of sulfur on raw agricultural commodities were ever submitted. Based on the toxicological data review completed for the development of this Standard, residue chemistry data are still not required.

Information from Canada indicates that the use of sulfur on raw agricultural commodities and food and feed items in Canada is exempt from the requirements of a tolerance and the use of sulfur according to good agricultural practices is recognized as safe.

No Maximum Residue Levels (MRL's) for residues from the use of sulfur on agricultural commodities are indicated by Codex Alimentaris.

Chapter VIII

Ecological Effects

Ecological Effects Profile: Manufacturing-Use Sulfur

There are six acceptable studies on the ecological effects of sulfur. These studies are sufficient to characterize sulfur non-toxic to the species tests. An 8-day dietary study on bobwhite quail reported a LC_{50} value of >180 ppm. The 48-hour LC_{50} for Daphnia magna is reported to be >5000 ppm and the 96-hour LC_{50} for mysid shrimp is between 646-839 ppm. Two beneficial insect studies demonstrated that sulfur (98% dust and 92% wettable powder) is low in toxicity to the honey bee through contact and ingestion.

Topical Discussions

Effect on Birds

The minimum data required are one avian acute oral LD_{50} study and two dietary data LC_{50} studies on wild waterfowl and upland game birds. No avian toxicity data are available on sulfur. A 8-day dietary study for bobwhite quail reported a LC_{50} value of >5620 ppm (Fink, 1982, GS0031-0003). No avian hazards have been reported and, therefore, the submission of further avian data and the avian dietary LC_{50} study for waterfowl are waived.

Effects on Fish

The minimum data required for establishing the acute toxicity of sulfur to fish are results from two 96-hour studies with technical sulfur, one using a coldwater species (preferably rainbow trout) and one using a warmwater species (preferably the bluegill sunfish).

There is sufficient information to characterize sulfur as practically non-toxic to warmwater fish (bluegill). The 96-hour LC_{50} value for a 99.5% sulfur formulation for bluegill fish and rainbow trout is >180 ppm. (U.S. EPA, 1975, GS0031-0004; 1976, GS0031-0005). No further data are required.

Effects on Aquatic Invertebrates

There is sufficient information to characterize sulfur as practically non-toxic to aquatic invertebrates. In a study, the 48-hour LC_{50} value for Daphnia magna is reported to be >5000 ppm (Borthwich and Stanley, 1982, GS0031-0002).

Effects on Estuarine and Marine Organisms

The minimum data required to establish the acute toxicity of sulfur to estuarine and marine organisms are 96-hour LC_{50} studies for shrimp and fish and either a 48-hour LC_{50} for embryo larval or a 96-hour LC_{50} shell deposition for molluscs.

There is sufficient information to characterize sulfur as practically non-toxic to estuarine invertebrates. In a study on mysid shrimp, the LC_{50} value for a 90% A.I. formulation of sulfur is reported to be between 646-839 ppm.

Effects on Beneficial Insects

Two studies on the effects of sulfur on beneficial insects were reviewed. The results of these studies are summarized below:

Table 1
Toxicity Studies on Beneficial Insects with Sulfur

Species	Formulation	Results	Citation
Honey bee (Apis mellifera)	98% Dust	Relatively non-toxic to honey bee	Atkins and Anderson, 1954, 05012143
Honey bee (A. mellifera)	92% WP	Low in toxicity through contact and ingestion	Arzone et al ., 1975, 05017191

Based on these results, sulfur is shown to be low in toxicity to honey bees.

Guide to Use in This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources, including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliograph is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

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   b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

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d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. Immediately following the word 'received' appears the date of the earliest known submission.

(2) Administrative Number. The next element, immediately following the word 'under', is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th 123456-Z; and 27th, 123456-AA.

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Vapor Pressure	Vapor pressure is 0.0070 mmHg at a mean barometric pressure of 740.7 mmHg and a temperature of 99.3°C; (Gruener, 1907, 05011817)
Stability	Amorphous sulfur is not stable at a temperature below 160°C. Depending on the ambient temperature, it either changes to orthorhombic or monoclinic crystalline sulfur. (Tuller, 1970, 05015159)
Oxidizing and Reducing Action	At room temperature, sulfur is not chemically active; when heated, sulfur combines with oxygen to form sulfur dioxide and sulfur trioxide.
Explosiveness	Sulfur will spontaneously ignite between 248°C and 266°C at atmospheric pressure in the presence of air and oxygen. (West, 1950, 05011811) A sulfur dust mixture with a concentration ranging from 0.035 oz/cu ft – 1.4 oz/cu ft of air will be ignited by a flame or spark.
Storage Stability	Sulfur is considered to be a stable compound (Tuller, 1970, 05015159)
Corrosion Characteristics	Sulfur combines directly with all metals, except gold and platinum (Tuller, 1970, 05015159).

Additionally, data concerning the ultraviolet band of sulfur and the infrared spectrum of sulfur are available (Gilles, 1929, 05016368; Taylor, 1929, 05011812).

Chapter V

Environmental Fate

Use Profile

Elemental sulfur is federally registered as both a fungicide and as an insecticide. As a fungicide, sulfur is registered for use on a broad range of agricultural crops and ornamentals to control powdery mildew, as well as numerous other foliar diseases and fruit rots. As an insecticide, sulfur is primarily used to control mites. It is estimated that between 135-190 million pounds of sulfur are used annually as a pesticide. The major high usage sites include: grapes, peaches, sugarbeets, and citrus.

At present, there are 148 federally registered products and 98 state registration containing sulfur as a single active ingredient fungicide. As an insecticide, there are 129 federally registered products and 70 state registrations. Sulfur is formulated into dusts (20-99.8% A.I.), wettable powders (30-97% A.I.), wettable powder/dusts (90-98.5% A.I.), and flowable concentrates (6 and 8 lb/gal). Insecticidal formulations also include an ointment for topical use, and a sulfur candle for use as a space fumigant.

Environmental Fate Profile

The data available are insufficient to allow a complete assessment of the environmental fate of elemental sulfur when applied as a pesticide. Sulfur is a component of the environment, and there is a natural cycle of oxidation and reduction reactions which transforms sulfur into both organic and inorganic products. Sulfur in the form of sulfate (HSO_4-) constitutes about 0.1% of U.S. soils. Elemental sulfur is slowly converted to sulfate in soil by the action of autotrophic bacteria. Sulfur is also used non-pesticidally as a soil amendment to correct sulfur deficiencies and to reduce soil pH; conversion to sulfate follows soil application and is necessary to achieve these results. The sulfate anion has been shown to leach through soil at a slow rate.

Since sulfur is a natural component of the environment and, in addition, has non-pesticidal applications, the testing requirements for environmental fate have been waived, with the exception of testing relating to reentry considerations. With respect to the reentry considerations, the registrant is required to propose an acceptable reentry interval based on one of the following: the longest, most restricting existing interval for sulfur; data on dissipation of foliar residues on human exposure to those residues, and on toxicity of sulfur; determination of that time beyond which there are no detectable, dislodgeable residues remaining in the worker environment.